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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,104	11/17/2003	Konstantin L. Valtchev	2-1861-027	3273
803	7590	11/19/2007		
STURM & FIX LLP 206 SIXTH AVENUE SUITE 1213 DES MOINES, IA 50309-4076			EXAMINER PATEL, TARLA R	
			ART UNIT 3772	PAPER NUMBER
			MAIL DATE 11/19/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/715,104

Applicant(s)

VALTCHEV, KONSTANTIN L.

Examiner

Tarla R. Patel

Art Unit

3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 1-10 and 15-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-12, 19 and 20 is/are rejected.
- 7) ☒ Claim(s) 13 and 14 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 November 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims.

Therefore, the Amended claim limitation that "a base secured to the uterine mobilizer" must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application

must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

2. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: The amended claim 11 has a limitation of a base "secured" to the uterine mobilizer, which is claiming that implies that the base is secured to the mobilizer at all times but rather is secured at the time of use. This Amendment has no support for such a permanent securement of the two in the originally filed specification (please see figs 1 and 2, page 7 lines 7-8).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. The amended claim 11 has a limitation of a base "secured" to the uterine mobilizer, which is claiming that implies that the base is secured to the mobilizer at all times but rather is secured at the time of use. This Amendment has no support for such a permanent securement of the two in the originally filed specification (please see figs 1 and 2, page 7 lines 7-8). There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Lipfert et al. (3,952,737).

With respect to claims 19 and 20, Lipfert et al. discloses an elastic diaphragm (58) made of silicone (column 3 lines 41-44) having passageway/ hole (48) for engaging a base of the device (see fig 2,3), first annulus surrounding hole, a membrane of annulus shape (see fig 1) bordering an outer circumference of the first annulus, a membrane being of

thinner material (column 3 lines 41-44) and an outer periphery being of thicker material than the membrane.

7. Claims 11 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Kohl (2,818,856).

Kohl discloses an apparatus for vaginal delineation and occlusion, comprising a solid closed ring (14a), a plurality of legs (24,22) to which the ring is operably, pivotally mounted (column 4 lines 37-42) and a base (26) for securing apparatus to the uterine mobilizer, the legs being operably affixed to the base (see fig 1).

With respect to claim 12, Lipfert et al. inherently discloses the length of legs being variable to permit the solid ring to tilt to accommodate various angle of a fornix (it is inherently variable by permitting resilient expansion of the arms 22 and 24, as disclosed in column 5 lines 41-55).

Allowable Subject Matter

8. Claims 13 and 14 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

9. The following is a statement of reasons for the indication of allowable subject matter: The subject matter of the independent claims could either

not be found or was not suggested in the prior art of record. The subject matter not found was a the variable-length legs an outer telescoping arm, pivotally affixed to the solid ring and an inner telescoping arm connecting the distal arm and the outer telescoping arm, the inner telescoping arm sliding into the outer telescoping arm, a spring tending to force the distal arm and the outer telescoping arm apart, wherein the outer arm of one of the pair of legs is attached to the ring at a point diametrically opposed to the outer arm of another of the pair of legs.

Response to Arguments

10. Applicant's arguments filed 9/4/07 have been fully considered but they are not persuasive with respect to claims 19 and 20. However, the arguments directed to claims 11 and 12 were persuasive. Please see new rejection above with respect to claims 11-12.

11. With respect to claims 19 and 20, Applicant's argument that the Lipfert discloses an elastic diaphragm which obstructs an opening of the cervical cup and allows the flow in one direction only, however applicant's silicone ring obstruct the vagina by its rim or outer periphery and does not allow flow in any direction. The examiner respectfully disagrees because

these features “silicone ring obstruct the vagina by its rim or outer periphery and does not allow flow in any direction” are not claimed.

12. With respect to claimed limitation of “disposed to engage” a base is directed toward the intended use, the structure of Lipfert et al. diaphragm is same and the claim do not provide distinct structural element for example sizes and shapes specifically to that of intended use and has been treated as an intended use recitation. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). Since the limitation have not been positively claimed, it is inherent that the diaphragm of Lipfert et al. meets structure required by claim.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Mohajer (4,821,741) discloses a barrier elastic contraceptive made of silicone.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE**

FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tarla R. Patel whose telephone number is 571-272-3143. The examiner can normally be reached on M-T 6-3.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on 571-272-4940.

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The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TP

Patricia Bianco
11/13/07

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